Humanistic Burden of Retinal Vein Occlusion: A Systematic Literature Review

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Disclosures

- Quan Dong Nguyen reports being a Scientific Advisory Board member for Bausch and Lomb, Genentech, and Regeneron Pharmaceuticals, Inc.
- Fabiana Q. Silva and Steven Sherman are employees of and stockholders in Regeneron Pharmaceuticals, Inc.
- Gillian Sibbring and Anna McCormick are employees of Prime
- This analysis was funded by Regeneron Pharmaceuticals, Inc. (Tarrytown, New York), who is the sponsor and participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
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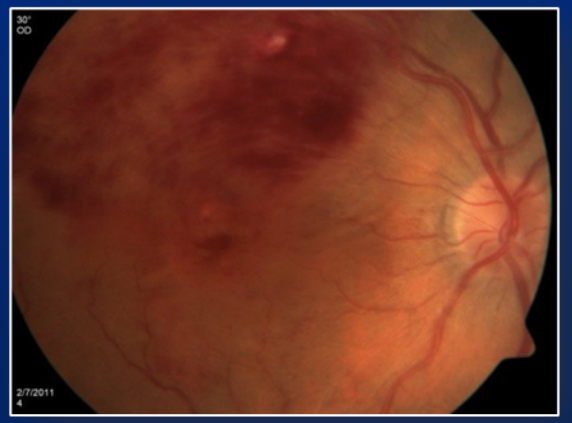
Background

- RVO (including its subtypes CRVO and BRVO) is the second most common retinal vascular disorder, affecting more than 28 million people worldwide[1,2]
- ME is a common visually threatening complication of RVO; ME is a major complication of CRVO, and 5%-15% of eyes with BRVO have been reported to develop ME over a 1-year period[3,4]
- Although the clinical burden of RVO is well-characterized, the impact of this disease on patients' QoL has not been well-explored

A systematic literature review was conducted to better understand the burden of RVO and reported impacts of treatment on humanistic outcomes



BRVO, branch retinal vein occlusion; CRVO, central retinal vein occlusion; HRVO, hemiretinal vein occlusion; ME, macular edema; RVO, retinal vein occlusion; QoL, quality of life.

1. Jaulim A et al. *Retina*. 2013;33:901-910. 2. Song P et al. *J Glob Health*. 2019;9:010427. 3.McIntosh R et al. *Ophthalmology*. 2010; 117:1113-1123. *4*. Rogers S et al. *Ophthalmology*. 2010;117:1094-1101.

Methods

A systematic literature review was conducted to retrieve relevant clinical data from published literature in accordance with the PICOS framework[1]

Database search:

Medline and Embase databases were searched via the Ovid search engine to identify relevant RCTs/ observational studies published from January 1, 1990, to March 16, 2022, and literature reviews/ meta-analyses published from January 1, 2017, until March 16, 2022

Grey literature search:

Abstracts presented at congresses within the last 2 years were searched using focused browsing and keyword searching of specific websites

Backwards citation searches:

Reference lists of published SLRs and meta-analyses meeting the eligibility criteria were reviewed to identify any relevant RCTs/observational studies that were not identified in the literature searches

PICOS, Population/Problem, Intervention, Comparison, Outcome, and Study design; RCT, randomized clinical trial; SLR, systematic literature review.

1. CRD's guidance for undertaking reviews in health care. Systematic Reviews. Centre for Reviews and Dissemination; 2009. Accessed October 17, 2023. https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf.

PICOS Framework: Inclusion criteria

Population/problem

- Adult patients (≥18 years old) with RVO (branch, central, or hemiretinal)

Intervention

- Untreated or best supportive care
- Any treatment, including but not limited to pharmacological treatment

Comparison

- Any intervention of interest, including active comparators
- Placebo or best supportive care

Outcome

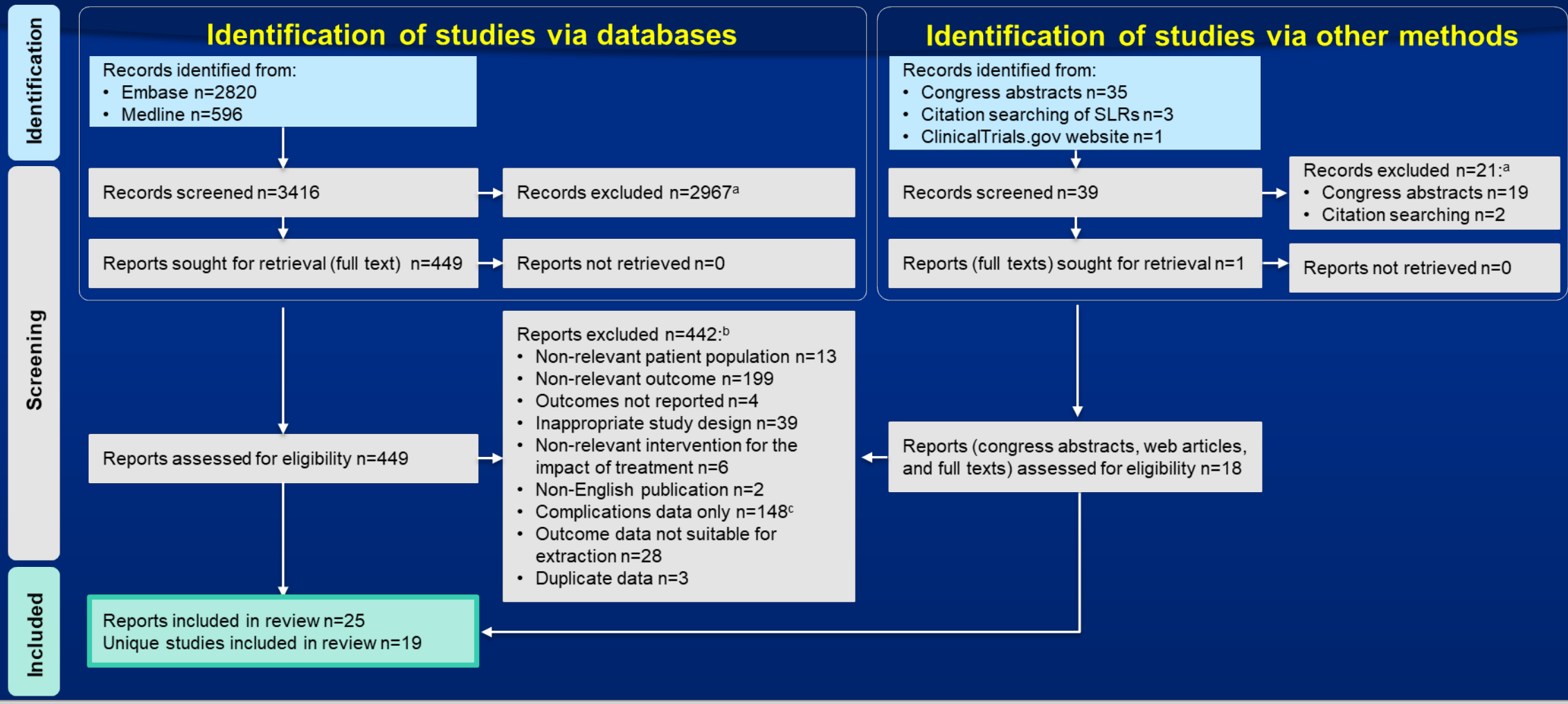
- **QoL:** Any humanistic outcome, including HRQoL and utilities
- **Ocular complications:** Incidence of ocular complications[a] were extracted only if HRQoL outcomes were also reported
- **PROs:** Injection number/frequency was extracted if correlation with QoL was reported; treatment-related pain or other patient experience; IOP was extracted if correlated with HRQoL or other PRO

Study design

- Observational studies, narrative literature reviews published since 2017[b]
- RCTs and observational studies since 1990, and for backwards citation searching, SLRs or meta-analyses published since 2017[c]

[a]Post-second pass protocol amendment; [b]For general review of humanistic burden; [c]For review of the impact of treatment on humanistic outcomes.
HRQoL, health-related quality of life; IOP, intraocular pressure; PRO, patient-reported outcome.
CRD's guidance for undertaking reviews in health care. Systematic Reviews. Centre for Reviews and Dissemination; 2009. Accessed October 17, 2023. https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf.

PRISMA Flow Diagram



Searches identified 3455 records from all sources: following screening per PRISMA guidelines, the final set of eligible publications consisted of 25 articles (19 unique studies) from which data were extracted

[a]Mostly due to non-relevant outcomes or inappropriate study design; [b]In the order that screening questions were asked; [c]Only studies reporting both complications and QoL outcomes were extracted and included in the analysis.

Outcomes Identified

NEI VFQ-25 scores

- General burden: Impact of RVO on NEI VFQ-25 composite and subscale scores
- Effect of treatment:
  - Change from baseline to post-treatment in NEI VFQ-25 composite scores in patients with RVO
  - Comparison of post-treatment NEI VFQ-25 composite scores in patients with RVO
  - NEI VFQ-25 subscale scores in patients with RVO
- Correlations between NEI VFQ-25 scores and VA or stereopsis

Utility measures

- VFQ-UI
- EQ-5D Index Score

Patient-reported pain

- Pain associated with intravitreal injection, as measured by VAS score
- Eye pain as an ocular complication

Ocular complications[a]

- Incidence of ocular complications

[a]Only if reported in studies also reporting QoL outcomes.
EQ-5D, EuroQol-5 dimensions; NEI VFQ-25, National Eye Institute Visual Function Questionnaire-25; VA, visual acuity; VAS, Visual Analog Scale; VFQ-UI, Visual Function Questionnaire-Utility Index.

Impact of RVO on NEI VFQ-25 Composite and Subscale Scores at Baseline

- Five publications of 4 studies (2 from SCORE 2 RCT in MEfRVO,[1-2] 3 in overall RVO: 1 prospective cohort study,[3] 1 case-controlled study,[4] and 1 cross-sectional study[5]) reported impact of different types of RVO on composite and subscale NEI VFQ-25 scores
- Three studies showed that patients with CRVO, HRVO, and BRVO had significantly lower NEI VFQ-25 composite and most subscale scores when compared with a control population[1,4-5]
- Patients with CRVO had worse HRQoL than patients with BRVO or HRVO in 2 studies[2,5]
- When comparing RVO with other ocular diseases, including nAMD and DME, NEI VFQ-25 composite scores and most subscale scores were higher in patients with CRVO or BRVO[3,5]

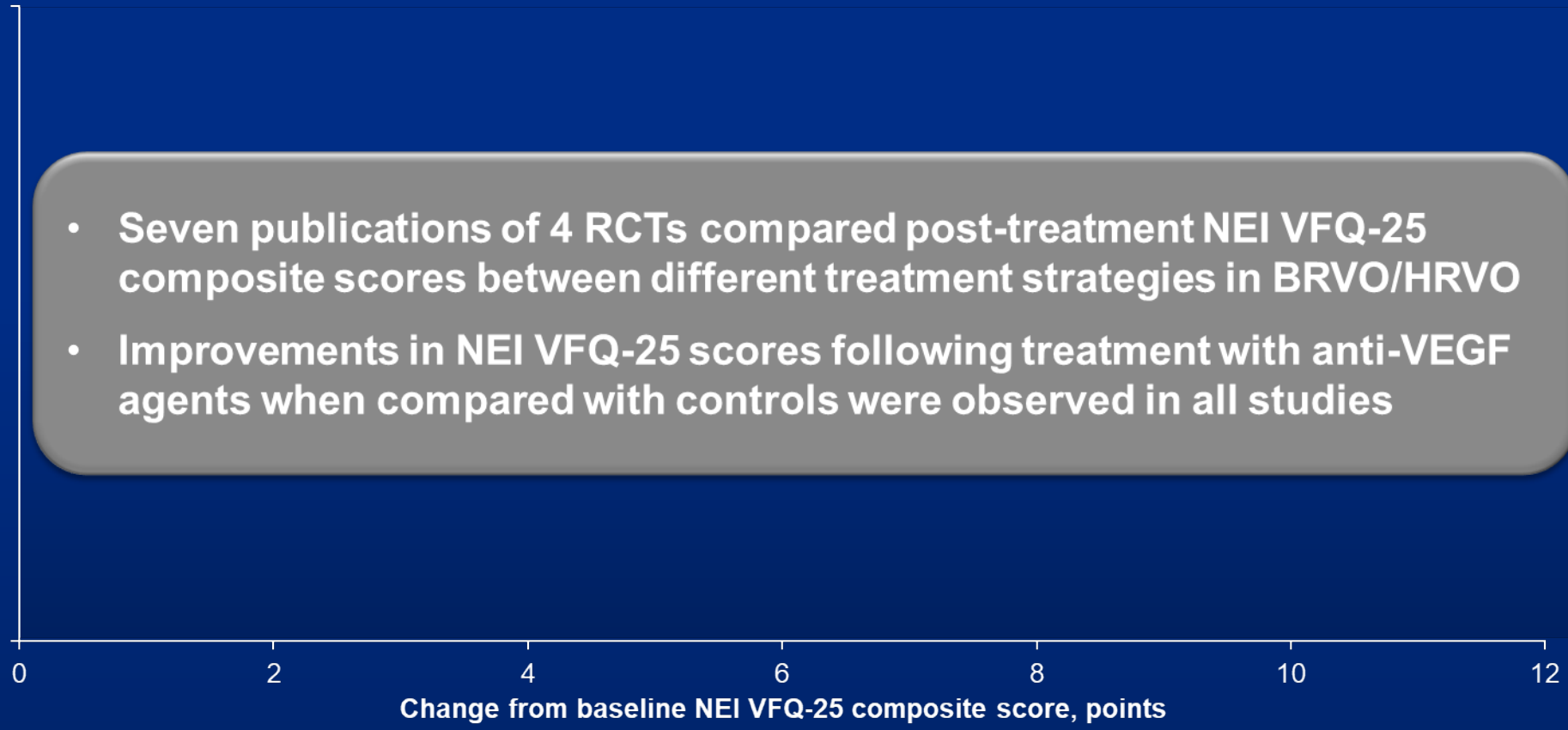
DME, diabetic macular edema; MEfRVO, macular edema following retinal vein occlusion; nAMD, neovascular age-related macular degeneration.

1. Scott IU et al. *Am J Ophthalmol*. 2017;184:147-156. 2. Scott IU et al. *JAMA Ophthalmol*. 2022;24:458-464. 3. Bertelmann T et al. *Health Qual Life Outcomes*. 2016;14:132. 4. Chatzirallis A et al. *Semin Ophthalmol*. 2021;36:658-664. 5. Awdeh RM et al. *Br J Ophthalmol*. 2010;94:319-323.

Post-treatment Change in NEI VFQ-25 Composite Scores Across Treatment Strategies (BRVO/HRVO)

Study	Study type	Patients
VIBRANT[1,2]	RCT	MEfBRVO/ MEfHRVO
BRAVO[3,4]	RCT	MEfBRVO
COMO[5]	RCT	BRVO
BRIGHTER[6,7]	RCT	BRVO

- Seven publications of 4 RCTs compared post-treatment NEI VFQ-25 composite scores between different treatment strategies in BRVO/HRVO
- Improvements in NEI VFQ-25 scores following treatment with anti-VEGF agents when compared with controls were observed in all studies



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Dex IV, dexamethasone intravitreal implant 0.7 mg at Day 1 and Month 5, with optional retreatment at Month 10 or 11; IAI, intravitreal aflibercept injection; IRI, intravitreal ranibizumab injection; M, month; MEfBRVO, macular edema following branch retinal vein occlusion; MEfHRVO, macular edema following hemiretinal vein occlusion; Q4W, every 4 weeks; PRN, when required; Q8W, every 8 weeks; VEGF, vascular endothelial growth factor; W, week.

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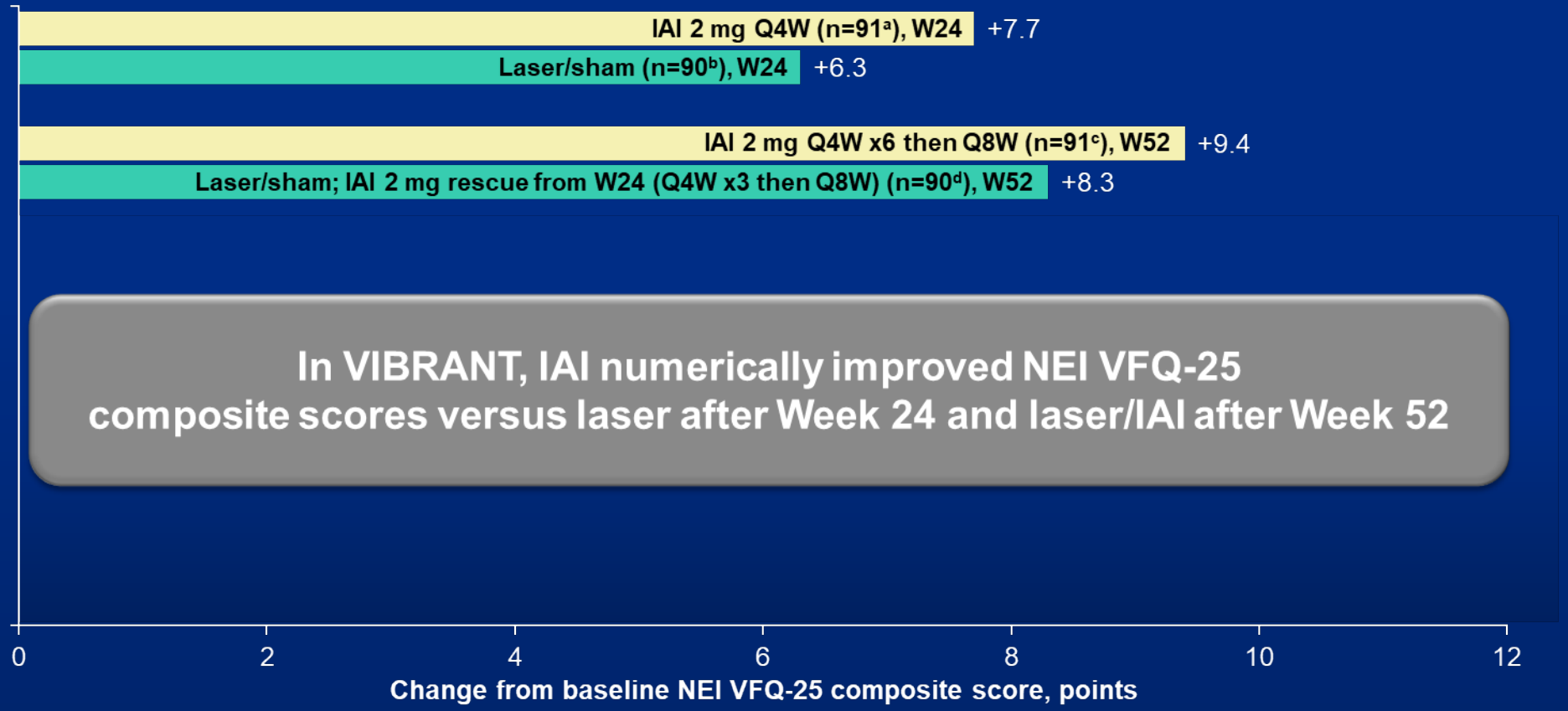

In VIBRANT, IAI numerically improved NEI VFQ-25 composite scores versus laser after Week 24 and laser/IAI after Week 52

[a]Eligible eyes received sham laser rescue at Week 12, 16, or 20; [b]Eligible eyes received 1 laser rescue from Week 12 to 20; [c]Eligible eyes received sham laser rescue at Week 12, 16, or 20; no treatment at Weeks 24, 28, 32, 40, 44, and 48; or active laser at Week 36; [d]Eligible eyes received 1 laser rescue from Week 12 to 20. From Week 24 to 48, eligible eyes received IAI 2 mg every 8 weeks after 3 initial monthly doses. At Week 36, eyes received sham laser in addition to IAI 2 mg; [e]$P<0.05$.
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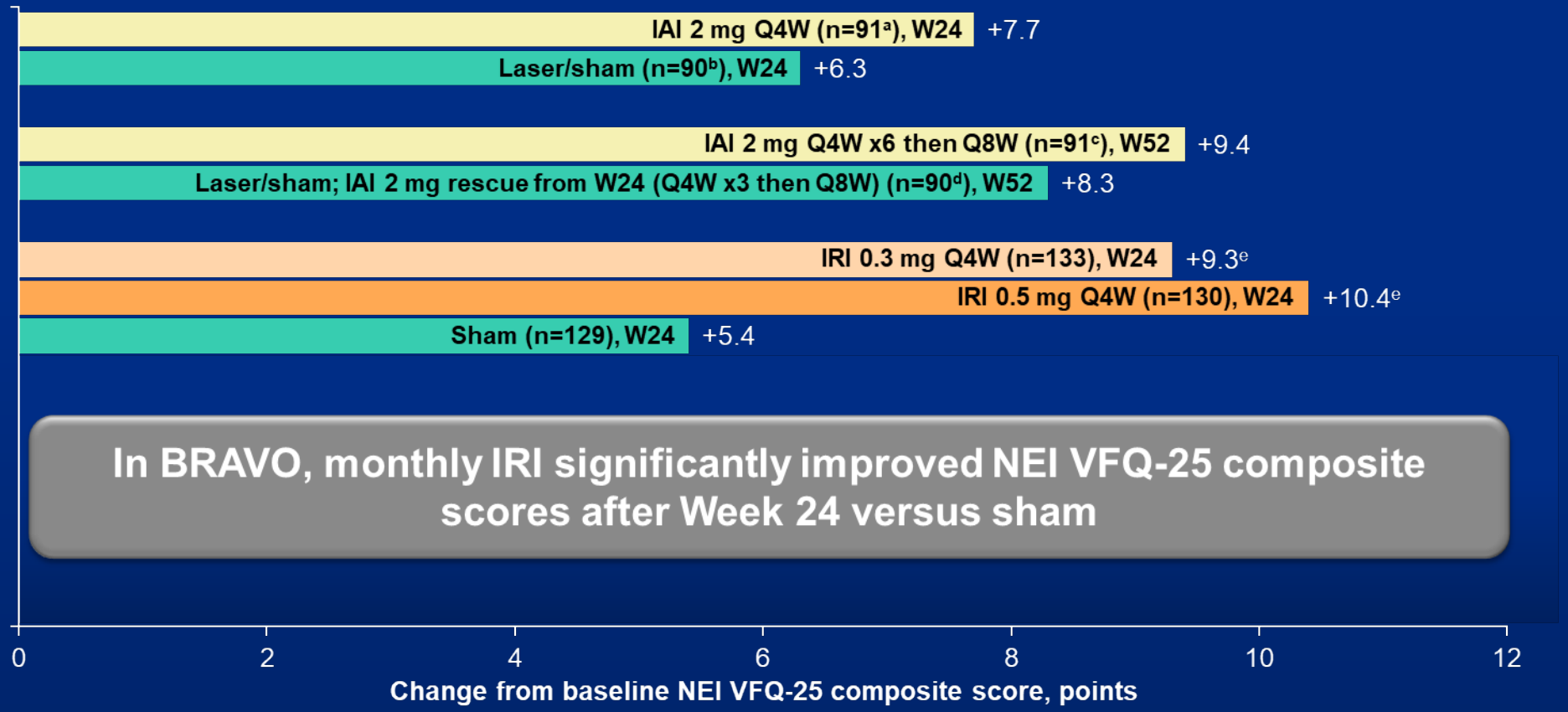

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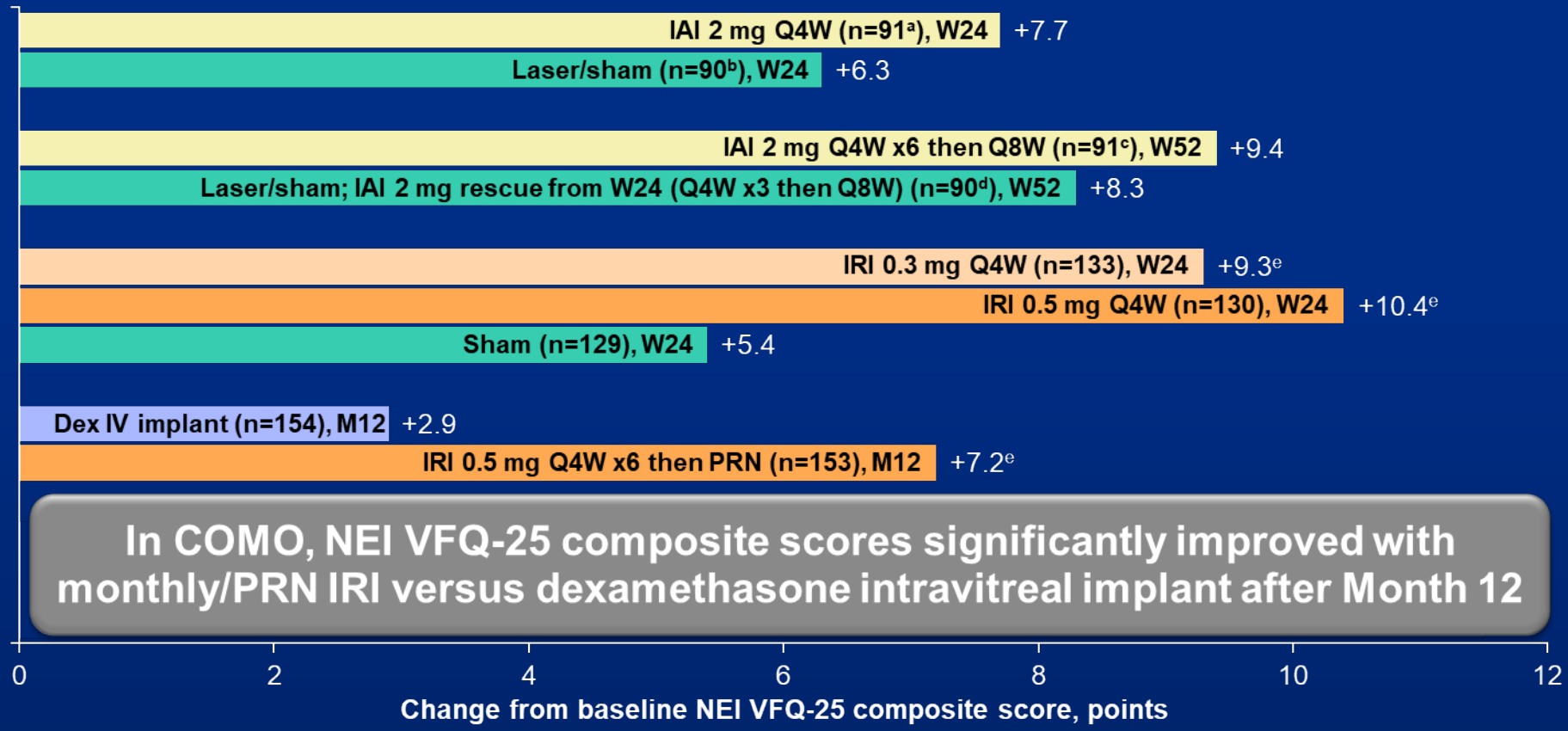

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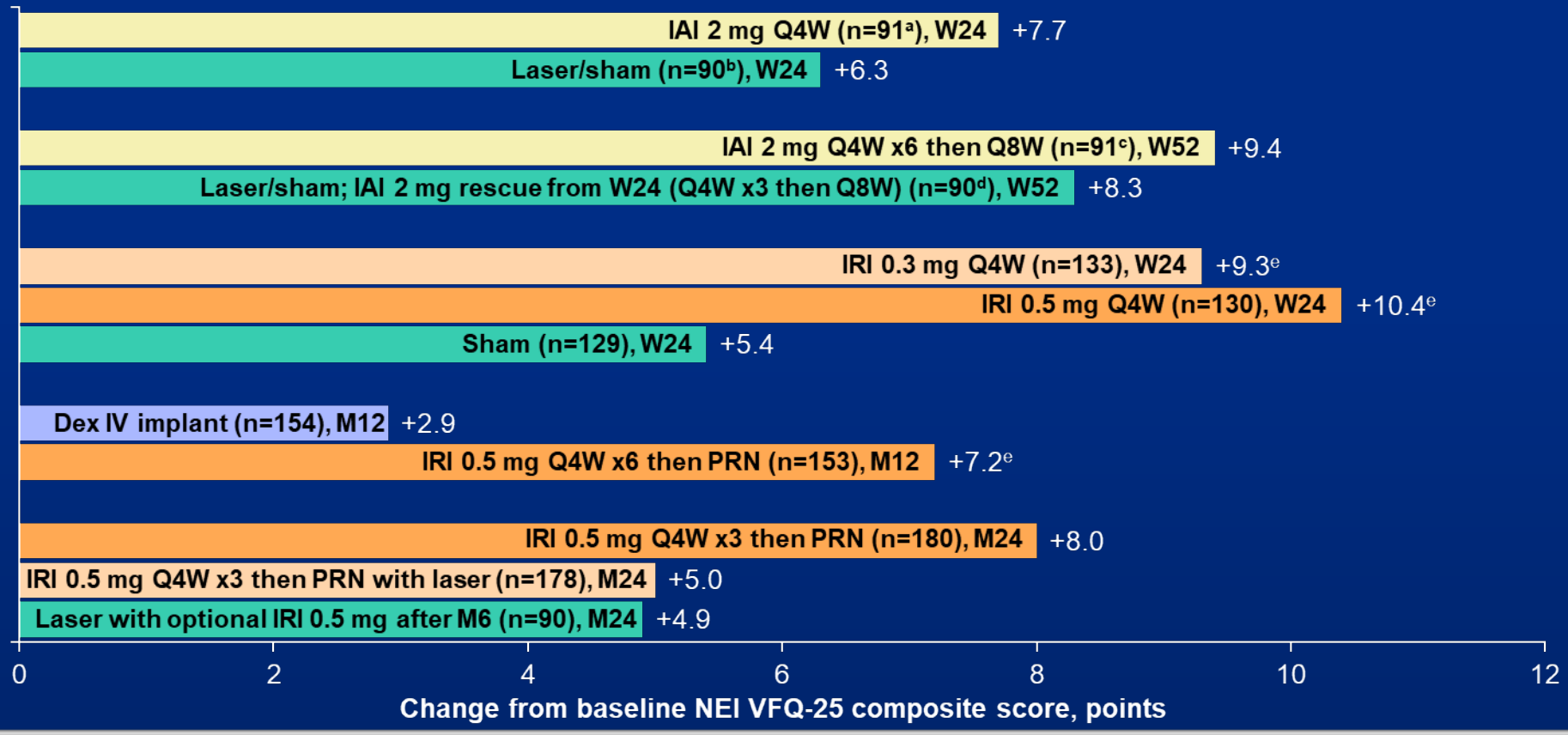

In BRIGHTER, IRI PRN numerically improved NEI VFQ-25 composite scores versus IRI/laser combination after Month 24

[a]Eligible eyes received sham laser rescue at Week 12, 16, or 20; [b]Eligible eyes received 1 laser rescue from Week 12 to 20; [c]Eligible eyes received sham laser rescue at Week 12, 16, or 20; no treatment at Weeks 24, 28, 32, 40, 44, and 48; or active laser at Week 36; [d]Eligible eyes received 1 laser rescue from Week 12 to 20. From Week 24 to 48, eligible eyes received IAI 2 mg every 8 weeks after 3 initial monthly doses. At Week 36, eyes received sham laser in addition to IAI 2 mg; [e]$P<0.05$.
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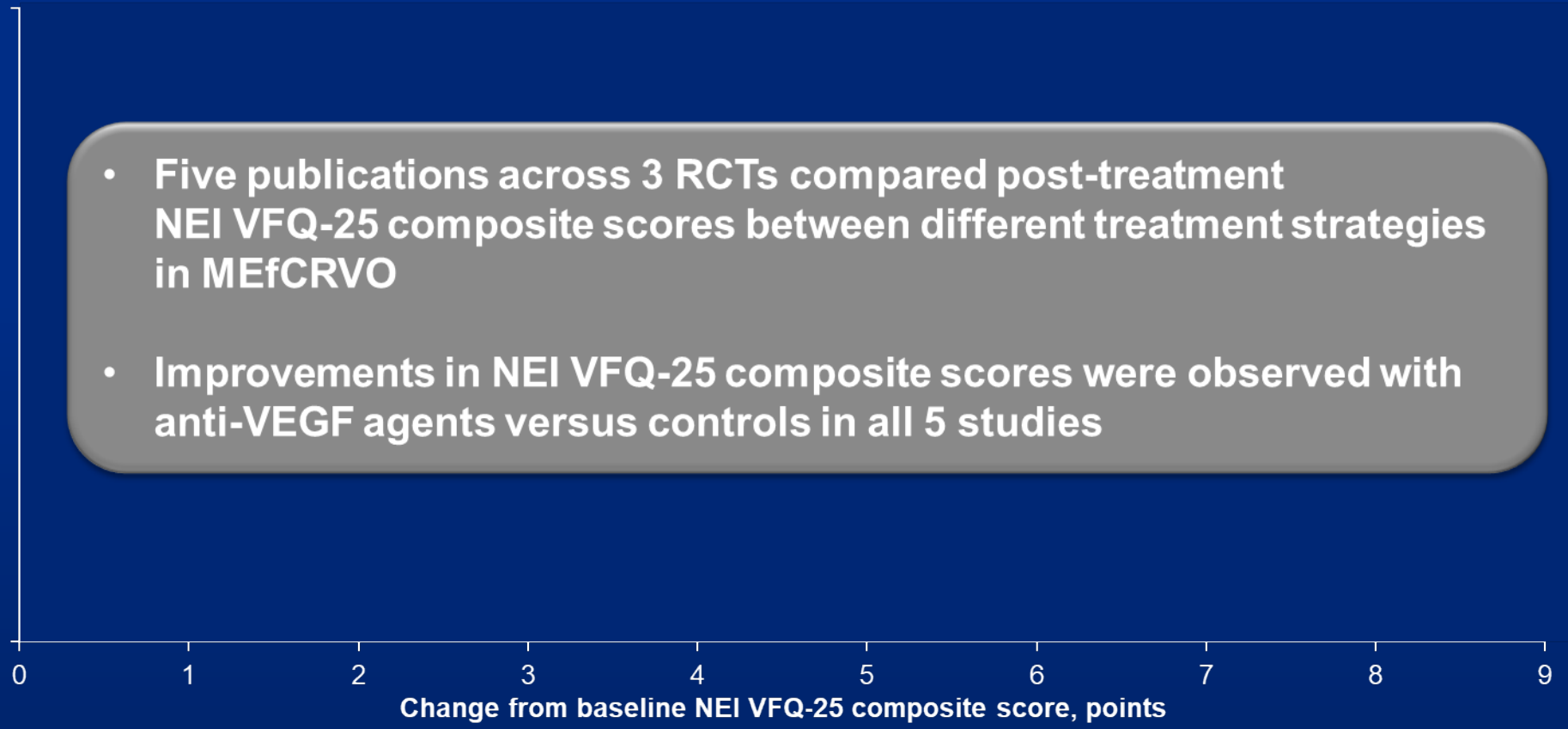
Post-treatment Change in NEI VFQ-25 Composite Scores Across Treatment Strategies (CRVO)

Study	Study type	Patients
CRUISE[1,2]	RCT	MEfCRVO
GALILEO[3,4]	RCT	MEfCRVO
COPERNICUS[5]	RCT	MEfCRVO

- Five publications across 3 RCTs compared post-treatment NEI VFQ-25 composite scores between different treatment strategies in MEfCRVO
- Improvements in NEI VFQ-25 composite scores were observed with anti-VEGF agents versus controls in all 5 studies



[a]*P*<0.01; [b]*P*<0.05 versus sham.

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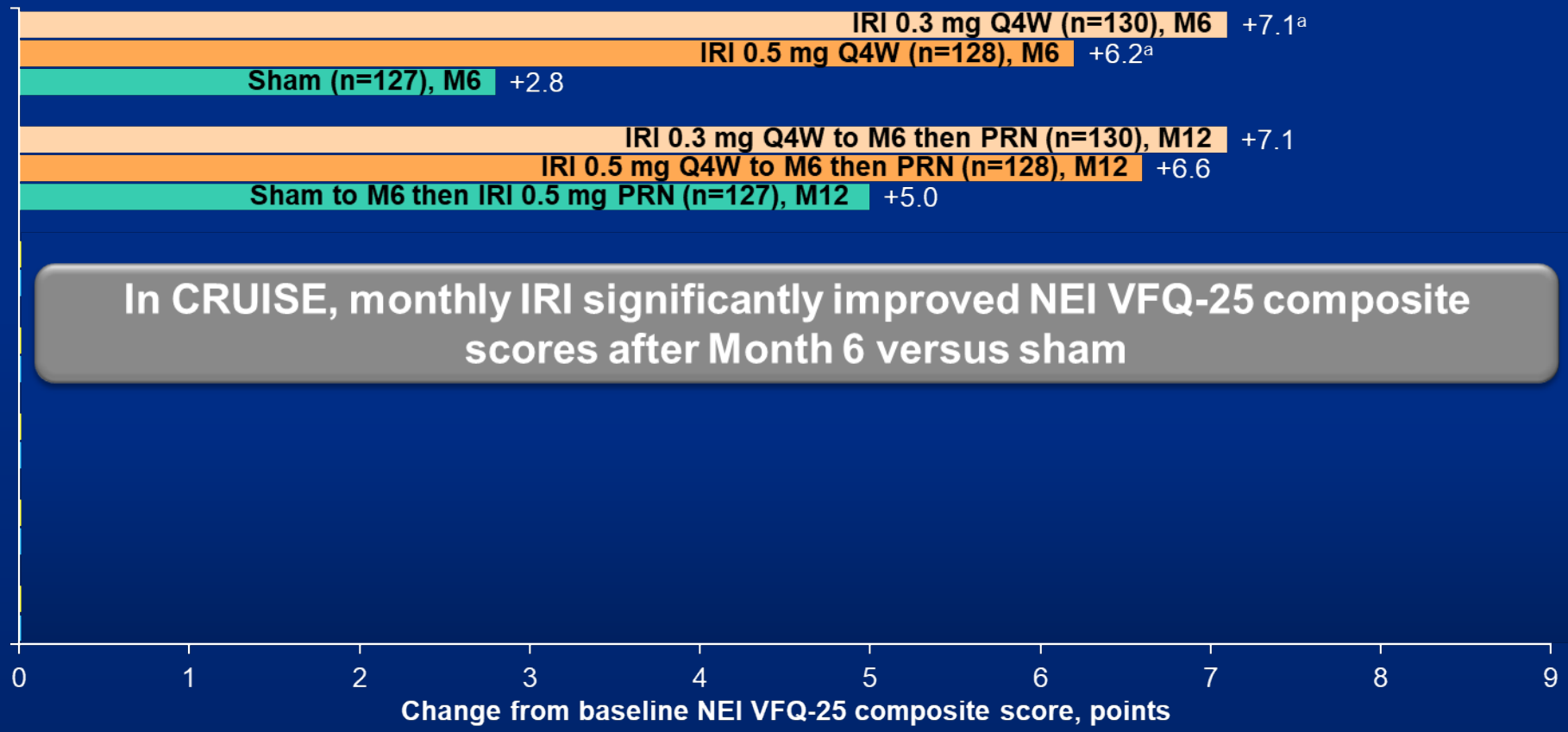

In CRUISE, monthly IRI significantly improved NEI VFQ-25 composite scores after Month 6 versus sham

[a]*P*<0.01; [b]*P*<0.05 versus sham.

1. Varma R et al. *Ophthalmology*. 2012;119(10):2108-2118. 2. Campochiaro PA et al. *Ophthalmology*. 2011;118(10):2041-2049. 3. Holz FG et al. *Br J Ophthalmol*. 2013;97(3):278-284.
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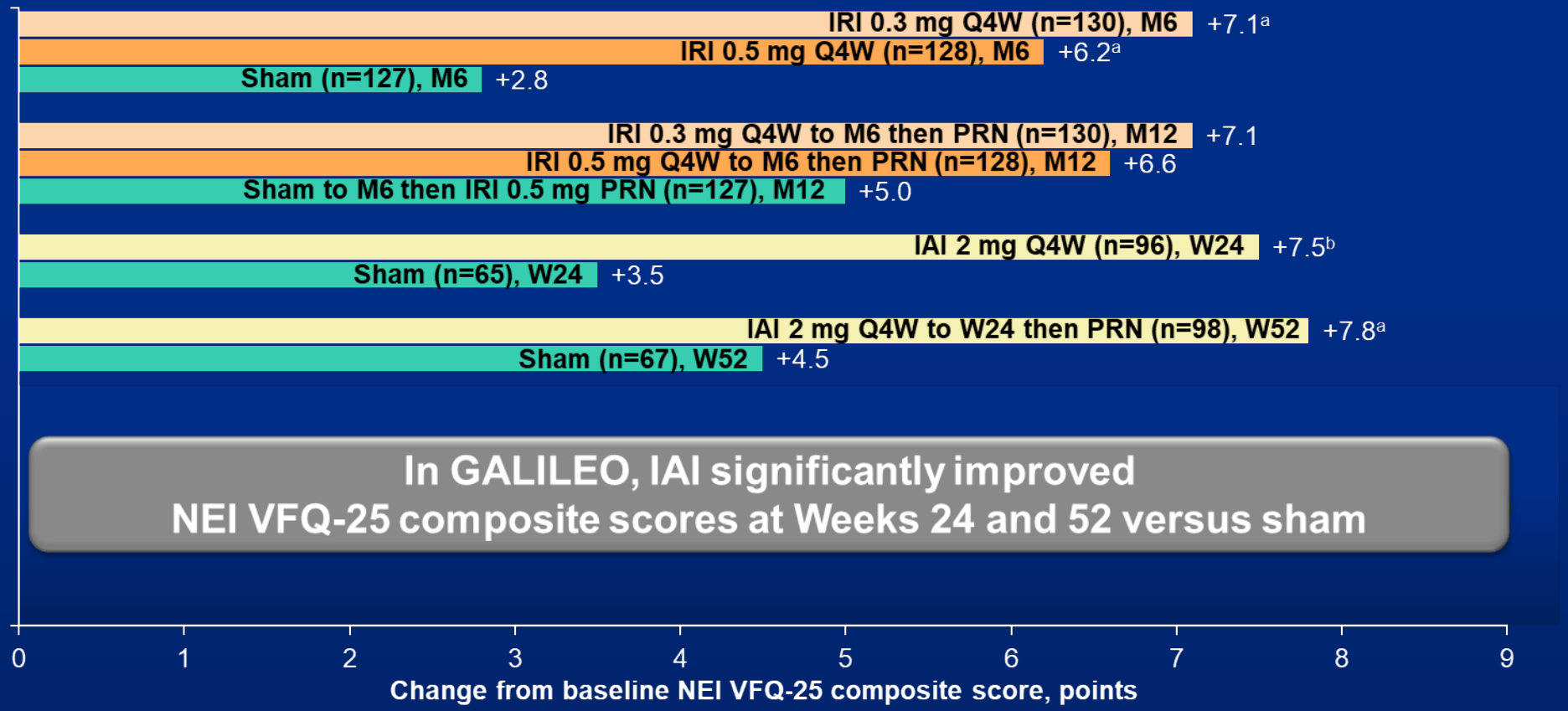

In GALILEO, IAI significantly improved NEI VFQ-25 composite scores at Weeks 24 and 52 versus sham

*P<0.01; †P<0.05 versus sham.

1. Varma R et al. *Ophthalmology*. 2012;119(10):2108-2118. 2. Campochiaro PA et al. *Ophthalmology*. 2011;118(10):2041-2049. 3. Holz FG et al. *Br J Ophthalmol*. 2013;97(3):278-284.
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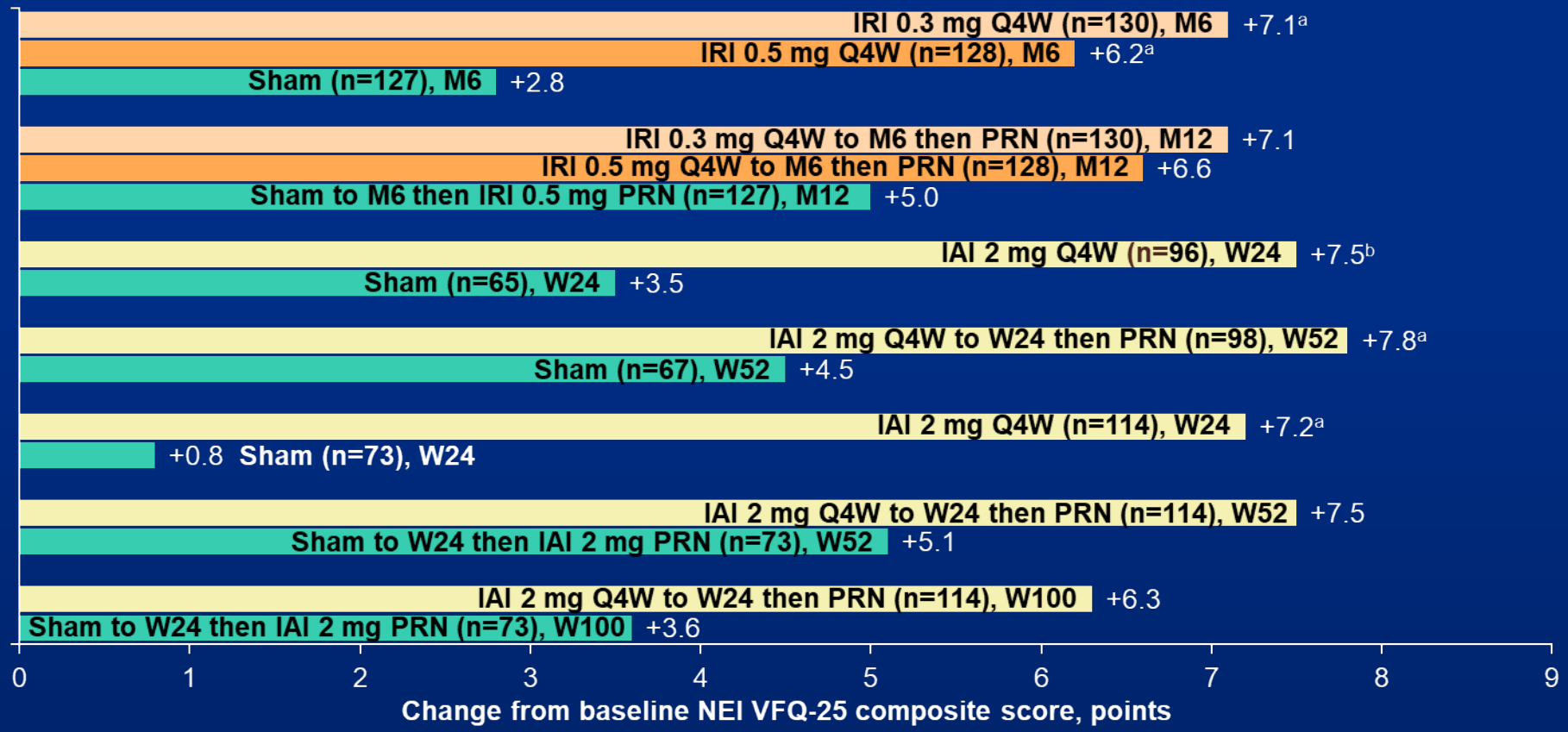

In COPERNICUS, monthly IAI significantly improved NEI VFQ-25 composite scores at Week 24 versus sham

[a]*P*<0.01; [b]*P*<0.05 versus sham.

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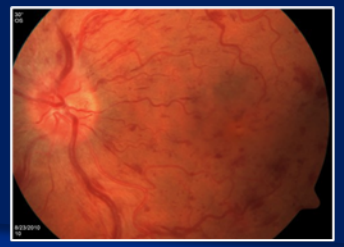
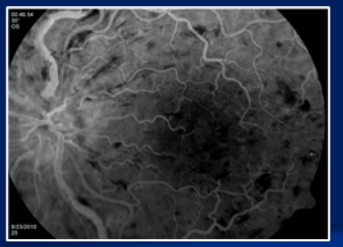
Summary of Other Findings

- NEI VFQ-25 scores at baseline were generally positively correlated with VA in the worse-seeing/affected eye in MEfBRVO;[1] improved NEI VFQ-25 composite scores after anti-VEGF treatment were correlated with improved VA in MEfCRVO and non-ischemic CRVO[2-4]
- NEI VFQ-25 subscale scores for near and distance activities were statistically or numerically improved with anti-VEGF treatment in RVO,[2,5-8] with subscale scores for mental health and driving also statistically improved in 2 studies[2]
- There was no significant change from baseline VFQ-UI with anti-VEGF in CRVO.[9] EQ-5D scores were improved with IAI versus sham in patients with MEfCRVO[7]
- Patient-reported pain with anti-VEGF injections was generally mild and occurred in relatively low proportions of patients.[8,10-13] No correlations between ocular complications and HRQoL measures were reported[6,7,11,12]

1. Morikawa S, et al. *BMJ Open Ophthalmol*. 2022;7:e000925. 2. Varma R et al. *Ophthalmology*. 2012;119(10):2108-2118. 3. Murakami T et al. *Br J Ophthalmol*. 2023; 107:254-260. 4. Okamoto F et al. *Sci Rep*. 2023;11(1):20475. 5. Campochiaro PA et al. *Ophthalmology*. 2015;122(3):538-544. 6. Clark WL et al. *Ophthalmology*. 2016;123(2):330-336. 7. Holz FG et al. *Br J Ophthalmol*. 2013;97(3):278-284. 8. Korobelnik JF et al. *Ophthalmology*. 2014;121(1):202-208. 9. Hykin P et al. *Health Technol Assess*. 2021;25:VII-111. 10. Crabb MG et al. *Clin Exp Ophthalmol*. 2013;41:7-27. 11. Doguizi S et al. *Eur J Ophthalmol*. 2018;28:63-67. 12. Larsen M et al. *Ophthalmology*. 2016;123:1101-1111. 13. Rifkin L et al. *Retina*. 2012;32:696-700.



Conclusions



- Only 25 articles published over a >30-year period were identified on the humanistic burden of RVO and the effect of treatment. Evidence for the impact of treatment on QoL in RVO was relatively strong; however, there was a lack of data on the additional burden of ME on QoL in patients with RVO and the effect of treatment
- QoL in patients with RVO was reduced compared with healthy individuals. QoL could be improved by IAI or IRI; dexamethasone intravitreal implant was inferior to anti-VEGF in improving QoL in a single study
- Initiation of anti-VEGF treatment in patients with MEfRVO may improve QoL, particularly related to near and distance activities
- Improvements in QoL after anti-VEGF treatment were correlated with improvements in VA in patients with RVO
- Evidence was available for all RVO subtypes; however, the impact of RVO and the effect of treatment on QoL was reported using NEI VFQ-25 scores only